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EXAMINER

KOLKER, DANIEL E

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/699,517	Applicant(s) SCHENK ET AL.	
	Examiner DANIEL KOLKER	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-46, 48, 51-55, 71-76 and 79-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-46, 48, 51-55, 71-76, 79-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/8/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The appeal brief filed 15 December 2008 has been entered. Claims 41 - 46, 48, 51 - 55, 71 - 76, 79 - 84 are pending.
2. The finality of the last office action is withdrawn. New rejections follow.

Withdrawn Rejections

3. The following rejections and objections set forth in the previous office action are withdrawn:

A. The rejection of claims 41 - 46, 48, and 51 - 55 for lack of enablement commensurate in scope with the claims is withdrawn in light of the arguments presented and upon reconsideration of the issues. The examiner concedes that it is within the skill of the artisan to treat patients suffering from Parkinson's disease by performing the methods as claimed. Note however the rejection of claims 71 - 76 and 79 - 84 for lack of enablement commensurate in scope with the claims is maintained.

Maintained Rejections

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 71 - 76 79 - 80 and 83 - 84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lessening the severity or delaying the outset of Parkinson's disease, does not reasonably provide enablement for prophylactically treating patients as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of

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experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

This rejection is maintained for the reasons previously made of record and explained in further detail below. Briefly, the claims subject to this rejection are drawn to prophylaxis of disease. The specification has specifically and expansively defined prophylactic treatment to not only include decreasing the severity of disease, or delaying its outset, but also to include administering a product "sufficient to eliminate... the risk... of the disease". See specification, paragraph [0137]. Thus, according to applicant's own definition, prophylaxis encompasses total elimination of risk of ever getting the disease.

Such complete elimination of risk is generally recognized as not possible. The specification fails to show actual working examples of elimination of risk of disease. While the specification (Example VI beginning on p. 63) does disclose data consistent with the conclusion immunization with A β attenuates the accumulation of certain Parkinson's disease-related products such as synuclein in transgenic mice, this is not the same as total elimination of risk of disease. To show this, the specification would have to show that animals immunized with the peptides as encompassed by the claims never have any risk for disease.

While the transgenic mice over-expressing human α -synuclein are a reasonable model for treatment of Parkinson's disease, these mice are not a reasonable model for prophylaxis of disease (the examiner is aware that certain examples in the specification also used doubly-transgenic mice which overexpress both synuclein and APP. As those mice do express synuclein at abnormally high levels, the same criticisms of the singly transgenic mice also apply to the doubly-transgenic mice; for the sake of simplicity only the singly-transgenic mice will be discussed here). The specification hypothesizes that since disease develops in mice over-expressing synuclein, and that since inducing the immune system to produce antibodies against this protein attenuates or delays disease in these mice, reduction of levels of α -synuclein is beneficial even in those patients who display no pathology or symptoms of Lewy body disease. While such logic is certainly reasonable in the case of immunizing against foreign pathogens such as viruses, which have no normal role in healthy physiology, given that α -synuclein is a naturally-occurring protein, decreasing the levels would be expected to have deleterious effects. At the time the invention was made, the art recognized the important role that α -synuclein has in promoting the health of neurons. For example, Alves da Costa (2003. *Current Molecular Medicine* 3:17-24) teaches that synuclein has roles in synaptic plasticity (p. 19, end of first

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column), and that it binds to synaptic vesicles (p. 19 second column). Alves da Costa teaches that the vesicle-binding property of synuclein may prevent it from forming toxic aggregates, suggesting that attenuating this function of the protein would lead to increased aggregate formation. Additionally, Alves da Costa teaches that α -synuclein protects against cell death, particularly programmed cell death. While pathogenic mutations can remove this phenotype (p. 20), in the absence of any such mutations (e.g. in patients with no family history of Parkinson's and wild-type synuclein sequences) it would be important to preserve this function.

Furthermore Sidhu (2004. FASEB J. 18:637 - 647) teaches that α -synuclein is expressed ubiquitously throughout the brain, suggesting it functions in a diverse set of neurophysiological processes, and that the protein constitutes up to 0.1% of all brain protein (see p. 637 second column). The reference also teaches that α -synuclein is important for regulating the synthesis and release of dopamine (p. 638 end of first column; see also p. 639 – 640). While certain aberrations can make the molecule toxic (pp. 642 – 643), the α -synuclein molecule itself was known to be important physiologically. Thus the art recognized that in normal healthy individuals, α -synuclein should not be attenuated.

The specification's use of transgenic mice over-expressing α -synuclein, and the observation that immunizing these mice with α -synuclein leads to an attenuation of anatomical changes seen in certain diseases, does not support enablement of the instant claims, which encompass eliminating risk of disease in asymptomatic, normal healthy patients.

At p. 11 of the Brief, applicant cites the non-precedential decision of the BPAI in *Ex Parte Saito*. According to applicant, the decision supports enablement of the claims under examination. In *Saito*, the Board reversed the examiner's rejection for lack of enablement. The board stated that although the claims encompassed treatment, which was not demonstrated and which the art recognized was difficult to achieve, the presence of difficult-to-achieve or non-enabled embodiments within the scope of the claim does not necessarily indicate the claim is not enabled. The examiner agrees that such logic may well apply in certain cases, such as *Saito*. However, when the number of non-enabled embodiments becomes large, the enablement of the claim as a whole is called into question. See MPEP § 2164.08(b). In the instant situation, the claims encompass so many embodiments that are recognized to be essentially impossible to achieve (elimination of risk and prevention of disease in asymptomatic patients) by means that are art-recognized to be deleterious, that they cannot reasonably be

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considered to be enabled over their full scope. For at least the above-stated reasons, the rejection for lack of enablement commensurate in scope with the claims stands.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 41 - 42, 45, and 51 - 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Jensen (U.S. Patent Application Publication 2002/0187157, published 12 December 2002, filed 20 February 2001, claiming benefit of a provisional application filed 1 March 2000, cited in office action mailed 7 April 2005).

Jensen teaches treating Parkinson's disease by administering A β protein along with an adjuvant that increases the immune response to the protein. See for example paragraphs [0055] - [0058], which teach immunization with naturally occurring amyloid proteins in order to down-regulate the amount of A β . Note that Jensen teaches that second moieties can also be introduced into the administered protein in order to increase immunogenicity; see for example paragraphs [0087] - [0082], [0104], [0121] - [0124] and [0126]. Alternatively, the protein can be administered along with an adjuvant; see for example paragraphs [0141] - [0145]. Beginning at paragraph [0177], Jensen specifically lists the diseases that can be treated by the described methods. While many of the working examples described in detail in the publication concern Alzheimer's disease (which is not particularly recited as a disease that is to be treated in the present claims), Jensen also clearly names Parkinson's disease as one of the disease to be treated. See paragraph [0181]. As Jensen teaches treating patients with Parkinson's by administering A β protein, either with a carrier or with an adjuvant, the reference anticipates every element of independent claim 41.

Claim 42 is anticipated as the agent can be A β protein. Jensen teaches peripheral administration at paragraph [0137], which is on point to claim 45. Claims 51 - 52 are anticipated

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as they recite effects which will necessarily occur upon administration, and do not require any additional starting materials or steps beyond those recited in independent claim 41.

At p. 14 of the Brief, applicant argues that Jensen does not teach administration of A β protein for treating Parkinson's disease. The examiner believes that the further explanations and citations of particular paragraphs, specifically paragraphs [0177] - [0181] from Jensen 2002/0187157, clarify that Jensen clearly conceived of treating Parkinson's disease by administering A β protein with adjuvants or carriers to increase immunogenicity, and that the reference provides detailed instructions on how to accomplish these steps.

New Rejections

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41, 43 - 44, 71, 73 - 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 41, 44, and 71 each are drawn to administration of an agent that induces an immunogenic response. Immunogenic agents are defined at p. 13 paragraph [0043] of the specification as those that induce immunological responses against themselves. That is, they are agents which elicit antibodies. However, claims 41, 44, and 71, as well as dependent claims 43 and 73, each are drawn to administration of antibodies. It is unclear whether the claims are drawn to methods of administering agents which induce antibodies, as required by the preamble, or methods of administering antibodies, as recited in the body of the claims.

Claim 74 is also confusing, but for a different reason. The claim ends with the phrase "...is administered with an adjuvant that augments an immune response to the agent, or an antibody to A β ." It is unclear whether the claim encompasses methods of administering antibodies or not. Does the phrase "or an antibody to A β " refer to one of the compounds that can be administered? Or does it refer to the immune response elicited? A skilled artisan could not determine if a method of administering an antibody to A β would infringe on claim 74 or not.

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Claim Rejections - 35 USC § 102

7. Claims 41, 43, 45, and 51 - 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Weksler (U.S. Patent Application Publication 2004/0197831, published 7 October 2004, Filed 14 March 2002, claiming benefit of a provisional application filed 16 March 2001).

Weksler teaches antibodies raised against A β peptide. See for example paragraph [0025] - [0027]. The reference also teaches that the antibody can be incorporated into a pharmaceutical composition (see paragraph [0033]) and administered to patients with certain specific diseases, including Parkinson's disease; see paragraph [0038]. The reference therefore teaches every element of claims 41 and 43, namely administering the appropriate anti-A β antibody to patients suffering from Parkinson's. Weksler teaches peripheral administration at paragraph [0137], which is on point to claim 45 (see paragraph [0035]). Claims 51 - 52 are anticipated as they recite effects which will necessarily occur upon administration, and do not require any additional starting materials or steps beyond those recited in independent claim 41.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 41 - 42, 45 - 46, 48, and 51 - 55, 71 - 72, 75 - 76, and 79 - 81 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen (U.S. Patent Application Publication 2002/0187157).

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The reasons why claims 41 - 42, 45, and 51 - 52 are anticipated by Jensen are set forth in the rejection under 35 USC 102(e) above. Jensen teaches peripheral administration at paragraph [0137], which is on point to claim 75. Jensen also teaches that in many cases, multiple doses of the antigen (i.e., A β) will be necessary, which is on point to claims 46 and 76 (see paragraph [0139]). However the reference does not explicitly teach administer multiple dosages over a period of at least six months as recited in claim 46 and 76, or administering to patients at risk of disease as recited in claim 48, or monitoring signs of disease as recited in claim 53, or administration to patients free of Alzheimer's and those with no risk of disease as recited in claims 54 - 55 and 79 - 80, or patients free of clinical symptoms of disease characterized by extracellular deposits as recited in claims 81 and 83. Additionally Jensen does not teach prophylaxis by administering to patients with known genetic risk as recited in claim 71.

Nonetheless, it would have been obvious to one of ordinary skill in the art to administer the A β proteins with carriers or adjuvants to patients with known risk of disease, as recited in claim 71 and 48. Jensen teaches that there are known genetic risks for Parkinson's (see paragraph [0044]), and since the method is taught to be effective in treating those patients with disease, it would have been obvious to administer it in sufficient doses to patients at risk of disease, in order to delay the outset or lessen the severity of symptoms. Therefore claims 48 and 71 - 72 are obvious. Claim 75 is included in this rejection as Jensen teaches peripheral administration. Claims 46 and 76 are obvious, as Jensen teaches administering multiple doses in the form of boosters (paragraph [0139]) and it is generally obvious to optimize the dosing schedule, even though the reference does not explicitly teach administering for at least six months.

Monitoring signs of disease as recited in claim 53 would have been obvious, in order to determine whether the patient needs a booster as taught in paragraph [0139]. Claims 54 - 55 and 79 - 80 are included in this rejection, since it also would have been obvious to one of ordinary skill in the art to treat patients free of Alzheimer's. Although Jensen does discuss treating Alzheimer's in some detail, the reference clearly teaches treating other diseases as well. Since Jensen teaches that other diseases including Parkinson's can be treated, it would be obvious to treat those conditions even when the patient does not have Alzheimer's or a risk of Alzheimer's. Claims 81 and 83 are included in this rejection as they depend from rejected claims 41 and 71 and further describe patients with Parkinson's who are free of Alzheimer's, as

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in claims 54 and 79, since extracellular amyloid deposits are characteristic of Alzheimer's disease.

10. Claims 41 - 42, 44 - 46, 48, and 51 - 55, 71 - 72, 74 - 76, and 79 - 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen (U.S. Patent Application Publication 2002/0187157) in view of Frangione (U.S. Patent 7,479,482, issued 20 January 2009, filed 21 November 2002, claiming benefit of a provisional application filed 21 November 2001).

The reasons why claims 41 - 42, 45 - 46, 48, and 51 - 55, 71 - 72, 75 - 76, 79 - 81 and 83 are either anticipated by, or obvious over, Jensen are set forth above and for the sake of brevity will not be repeated here. However, Jensen does not explicitly teach coadministering an agent that induces an immunogenic response against α -synuclein, as recited in claims 44 and 74.

Frangione teaches and claims administering peptides which induce antibodies against α -synuclein in order to treat Parkinson's disease. See for example column 22 line 31 - column 23 line 5, column 14 lines 21 - 34, and column 15 lines 25 - 42. This is on point to claims 44 and 74. However Frangione does not teach administering A β to patients with Parkinson's disease. Nonetheless it would have been obvious to one of ordinary skill in the art to coadminister the immunogenic fragments of α -synuclein from Frangione along with A β as taught by Jensen, thereby arriving at the inventions of claims 44 and 74. It is prima facie obvious to coadminister two compositions known to be effective for treating the same disease; in this case the prior art references by Jensen and by Frangione each teach administering these products for treating Parkinson's, thus combining them into a single composition would have been obvious. Claims 82 and 84 are included in this rejection as they depend from rejected claims 45 and 74 and further describe patients with Parkinson's who are free of Alzheimer's, as in claims 54 and 79.

11. Claims 41, 43, 45, 51 - 52, 71, 73, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weksler (U.S. Patent Application Publication 2004/0197831, cited above).

The reasons why claims 41, 43, 45, and 51 - 52 are anticipated by Weksler are set forth above. Weksler also teaches that the antibodies disclosed can be used for treating patients at risk of neurodegenerative diseases (see paragraph [0032] for example), but does not explicitly teach administering to patients at risk of Parkinson's and with known genetic risk of disease.

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Nonetheless, it would have been obvious to administer the same antibodies to patients with known genetic risk of disease, as doing so would attenuate the severity of disease. Since Weksler teaches that the antibodies can treat Parkinson's and can be administered to patients at risk of neurodegenerative disease in general, the artisan of ordinary skill would have had a reasonable expectation of success in administering the same product to patients with known genetic risk of Parkinson's. Therefore the methods of claims 71, 73, and 75 are obvious.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 2, 4 - 24 of U.S. Patent No. 6,787,523. Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating

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Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

13. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 2, 4 - 33, 35 - 63 of U.S. Patent No. 7,014,855 as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits, according to Primavera (see in particular abstract, Figure 4, and p. 189 first column).

14. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 3, 5 - 37, 39 - 53, 55 - 88, 90 100 of U.S. Patent No. 6,972,127 as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

15. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11 - 21, 23 - 45, and 47 - 60 of U.S. Patent No. 6,946,135 as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

16. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 5, 7 - 26, 28 - 44, 46 - 63, 65 - 80 of U.S. Patent No. 6,866,850 as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006).

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Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

17. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 2, 4 - 38, 40 - 60 of U.S. Patent No. 6,866,849 as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

18. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 - 9, 11 - 24 of U.S. Patent No. 6,787,144 (reference 14 on IDS filed 6 December 2007) as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

19. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 - 9, 11 - 24 of U.S. Patent No. 6,787,143 (reference 15 on IDS filed 6 December 2007) as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

20. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1

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- 2, 4 - 43 of U.S. Patent No. 6,787,140 (reference 16 on IDS filed 6 December 2007) as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

21. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 3, 5 - 38, 40 - 52 of U.S. Patent No. 6,787,139 (reference 17 on IDS filed 6 December 2007) as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

22. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11 - 21, 22 - 36 of U.S. Patent No. 6,787,138 (reference 18 on IDS filed 6 December 2007) as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

23. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 33 of copending Application No. 11/842120 as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 33 of copending Application No. 11/842113 as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 41 - 42, 45 - 46, 48, 51 - 55, 71 - 72, 75 - 76, and 79 - 84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 33 of copending Application No. 11/842085 as evidenced by Primavera 1999 (Journal of Alzheimer's Disease 1:183-193, cited in office action mailed 15 May 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating Parkinson's disease by administering A β protein, as Parkinson's is a disease characterized by amyloid deposits.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

26. No claim is allowed.

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Masliah 2001 (Proc Natl Acad Sci USA 98:12245-12250, cited as reference AV on IDS filed 31 October 2003). The reference teaches that administering A β peptide to cells expressing α -synuclein induces formation of aggregates of α -synuclein. This suggests that certain modes of administration, such as intracranial recited at paragraph [0142], of these peptides will not be effective as they will result in direct contact between A β peptide and the cells expressing synuclein. However the present claims exclude such routes of administration,

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as they require administration of "an effective regime of an agent" (see independent claims 41, 44, 71, and 74), and intracranial administration would not be effective.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker/

Primary Examiner, Art Unit 1649

March 12, 2009